

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 1085-16
Program	Prior Authorization/Notification
Medication	Ravicti® (glycerol phenylbutyrate oral liquid)
P&T Approval Date	04/2013, 4/2014, 4/2015, 2/2016, 12/2016, 12/2017, 12/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024, 2/2025
Effective Date	5/1/2025

**1. Background**

Ravicti (glycerol phenylbutyrate) is a nitrogen-binding agent indicated for chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).

Ravicti is not indicated for treatment of acute hyperammonemia in patients with UCDs. The safety and efficacy for treatment of N-acetylglutamate synthase (NAGS) deficiency has not been established.<sup>1</sup>

Coverage for Ravicti will be provided for patients who meet the following criteria:

**2. Coverage Criteria<sup>a</sup>:**

**A. Initial Authorization**

1. **Ravicti** will be approved based on **all** of the following criteria:

a. Diagnosis of urea cycle disorders (UCDs)

**-AND-**

b. Inadequate response to **one** of the following:

- (1) Dietary protein restriction
- (2) Amino acid supplementation

**-AND-**

c. Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Ravicti** will be approved based on **both** of the following criteria:

a. Documentation of positive clinical response to Ravicti therapy

**-AND-**

b. Patient is actively on dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Medical Necessity and/or Step Therapy may be in place.

**4. References:**

1. Ravicti<sup>®</sup> [package insert], Lake Forest, IL: Horizon Therapeutics, Inc.; September 2021.

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<b>Change Control</b>	
4/2014	Annual review with no change to clinical coverage. Updated reference.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
4/2015	Annual review with no change to clinical coverage. Updated background and reference.
2/2016	Annual review with no change to clinical coverage. Updated reference.
12/2016	Annual review. Updated background, formatting and reference.
12/2017	Annual review with no change to clinical coverage. Updated background and reference.
12/2018	Administrative change to add statement regarding use of automated processes.
12/2018	Annual review. No changes to clinical coverage criteria.
2/2019	Updated background and criteria to align with updated indication allowing use in patients less than 2 months of age.
2/2020	Annual review with no change to clinical coverage. Updated reference.
2/2021	Annual review with no change to clinical coverage.
2/2022	Annual review with no change to clinical coverage. Updated reference.
2/2023	Annual review with no change to clinical coverage. Added state mandate footnote.
2/2024	Annual review with no change to clinical coverage.
2/2025	Annual review with no change to clinical coverage.